JMR/2011R00374

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	**CRIMINAL NO.** 15-616-NLH
v.	:	**18 U.S.C. § 371** **18 U.S.C. § 545**
MERWIN MARC SNYDER	:	**21 U.S.C §§ 331(a), (c), (k)** **Notice of Forfeiture**

INDICTMENT

The Grand Jury in and for the District of New Jersey, sitting at Camden, charges:

COUNT 1
[18 U.S.C. § 371 – Conspiracy]

1. At all times relevant to this Indictment:

The Defendant

a. Defendant **MERWIN MARC SNYDER** was a resident of Egg Harbor Township, New Jersey. Defendant **SNYDER** repackaged and dispensed to individual customers in the United States misbranded and unapproved prescription drugs that had been smuggled in wholesale quantities into the United States. Customers ordered these drugs through various internet websites, including md-u.com and promptpillstore.com.

b. Defendant **MERWIN MARC SNYDER** did not possess a valid wholesale drug distribution license, a valid pharmacy license, or a license to prescribe prescription drugs in the State of New Jersey.

The United States Food And Drug Administration, Definitions And Regulations

c. The United States Food and Drug Administration ("FDA") was the federal agency within the executive branch of the government responsible for protecting the health and

safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"). Among the purposes of the FDCA was to assure that drugs sold for human use were safe, effective, and bore accurate labeling containing all required information. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

d. Under the FDCA, drugs were defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease in humans (21 U.S.C. § 321(g)(1)(B)); articles intended to affect the structure or function of the body of humans (21 U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

e. The term "label" was defined as a display of written, printed, or graphic matter upon the immediate container of any article. (21 U.S.C. § 321(k)). The term "labeling" was broader, and included all labels and other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. (21 U.S.C. § 321(m)).

f. Prescription drugs were defined under the FDCA as: (a) those drugs which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drug; and (b) those drugs limited by an FDA-approved application to use under the professional supervision of a licensed medical practitioner (21 U.S.C. §§ 353(b)(1)(A),(B)).

g. The FDCA prohibited the introduction or delivery for introduction, or to cause the introduction or delivery for introduction, into interstate commerce of a misbranded drug. (21 U.S.C. § 331(a)). It was also a prohibited act under the FDCA to receive a misbranded

drug in interstate commerce, and to deliver or proffer delivery of that drug for pay or otherwise. (21 U.S.C. § 331(c)). It was also prohibited to do any act that caused a drug to become misbranded while it was held for sale (whether or not the first sale) and after it had moved in interstate commerce. (21 U.S.C. § 331(k)).

h. A drug was misbranded if, among other things:

i. its labeling was false or misleading in any particular manner (21 U.S.C. § 352(a)); or

ii. its labeling did not bear adequate directions for use (21 U.S.C. § 352 (f)(1)); or

iii. it was an imitation of another drug (21 U.S.C. § 352(i)(2)), or

iv. it is offered for sale under the name of another drug (21 U.S.C. § 352(i)(3)); or

v. the drug was a prescription drug dispensed without the valid prescription of a practitioner licensed by law to administer such drug (21 U.S.C. § 353(b)(1)).

i. A drug was misbranded unless its labeling bore adequate directions for its use. Adequate directions for use were further defined by regulation as "directions under which the layman can use a drug safely and for the purposes for which it is intended." (21 C.F.R. § 201.5). Because prescription drugs by definition could only be safely used under the supervision of a licensed medical practitioner, they had to qualify for an exemption to this labeling requirement to be legally distributed in interstate commerce. The exemption was set forth in Title 21, Code of Federal Regulations, Section 201.100, which stated that a prescription drug would be exempt from the requirement of Title 21, United States Code, Sections 352(f)

(that its labeling contain adequate directions for use) if all the conditions of the exemption were met, including: (1) that the drug be in the possession of persons regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (2) in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in dispensing prescription drugs; or (3) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (4) the drug was to be dispensed pursuant to a valid prescription. In addition, if the drug was one required under the FDCA to have an approved application prior to distribution, the drug had to bear the FDA-approved labeling.

j. A prescription drug had to be dispensed only upon the written prescription of a practitioner licensed by law to administer such drug, or upon an oral prescription of such practitioner which was reduced promptly to writing and filed by the Pharmacist. The act of dispensing a drug contrary to these requirements resulted in that drug being misbranded while held for sale. (21 U.S.C. § 353(b)).

k. The FDCA provided that before a new drug could be distributed in interstate commerce, its manufacturer had to obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans). (21 U.S.C. §§ 355(b),(j),(i)). To receive approval to market a drug, the manufacturer had to submit information showing that the new drug was safe and effective for its intended use, 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50 or for generics to show bioequivalence to the pioneer (brand name) drug. (21 U.S.C. § 355(j)).

The Drugs

l. "Viagra" was a drug within the meaning of Title 21, United States Code, Sections 321(g)(2),(3) and a prescription drug within the meaning of Title 21, United States

Code, Section 353(b)(1)(B). Viagra was the trade name for Pfizer, Inc.'s FDA-approved erectile dysfunction drug containing the active ingredient sildenafil citrate. FDA has not approved any generic drugs containing sildenafil citrate, including those with the labeled trade names "Filagra, Sildigra, or Viprogra."

m. "Cialis" was a drug within the meaning of Title 21, United States Code, Sections 321(g)(2),(3) and a prescription drug within the meaning of Title 21, United States Code, Section 353(b)(1)(B). Cialis was the trade name for an FDA-approved erectile dysfunction drug manufactured by Eli Lilly & Company that contained the active ingredient tadalafil. FDA had not approved any generic drugs containing tadalafil nor any drug with the trade name "Tadalista."

n. "Levitra" was a drug within the meaning of Title 21, United States Code, Sections 321(g)(2),(3) and a prescription drug within the meaning of Title 21, United States Code, Section 353(b)(1)(B). Levitra was the trade name for an FDA-approved prescription erectile dysfunction drug manufactured and co-marketed by Bayer Pharmaceuticals, GlaxoSmithKline, and Schering-Plough that contained the active ingredient Vardenafil. The FDA has not approved any generic drug containing Vardenafil nor any drug with the trade name "Filitra."

o. "Mifepristone" was a drug within the meaning of Title 21, United States Code, Section 321(g)(2),(3) and a prescription drug within the meaning of Title 21, United States Code, Section 353(b)(1)(B). Mifepristone was the trade name for an FDA-approved drug to terminate intrauterine pregnancies of up to 49 days gestation manufactured by Danco Laboratories. Mifepristone was a prescription drug, but it was not available to the public through pharmacies; its distribution was restricted to specially qualified, licensed physicians. Under the

FDA-approved regimen, a 600 milligram dose of Mifepristone was administered by a clinician following a counseling session. Two days later, a clinician would administer 400 micrograms of another drug, misoprostol, to induce contractions. Misoprostol was manufactured by Ivax Sub Teva Pharmaceuticals and Novel Labs, Inc. A "Mifepristone and Misoprostol Combipack" was not FDA-approved for sale by prescription or over the counter.

Internet – Based Marketing of Drugs

p. Various websites hosted overseas for sale certain prescription drugs popular in the United States including what were represented as generic formulations of Viagra, Cialis, Levitra, Mifepristone and Misoprostol containing the active ingredients of the brand name drugs. These internet websites did not request a prescription from a licensed medical practitioner prior to filling the order.

The U.S. Department of Homeland Security – Customs and Border Protection and Importation into the United States

q. The Department of Homeland Security, Customs and Border Protection ("CBP") was the agency commissioned to receive and collect excise tax on behalf of the United States Department of Treasury and the Internal Revenue Service at the point of entry (port) for imported goods.

r. An importer of record was the individual or entity liable for duties, taxes, and fees on merchandise imported into the United States. The importer of record was responsible for filing entry documents with the CBP which classified the imported merchandise, identified its value and provided any other information necessary to enable CBP to assess duties properly, collect accurate statistics, and determine whether other applicable legal requirements, if any, had been met.

The Conspiracy

2. From on or about May 7, 2010 through on or about July 25, 2013, in Atlantic County, in the District of New Jersey and elsewhere, defendant

MERWIN MARC SNYDER

did conspire and agree with others to:

a. Knowingly import and bring into the United States merchandise contrary to law, specifically misbranded drugs, contrary to Title 18, United States Code, Section 545; and to

b. Introduce and deliver into interstate commerce misbranded prescription drugs, contrary to Title 21, United States Code, Section 331(a).

Object of the Conspiracy

3. The object of the conspiracy was for defendant **MERWIN MARC SNYDER** and his co-conspirators to unlawfully enrich themselves by distributing and dispensing unapproved generic formulations of prescription drugs popular in the United States without the involvement of licensed medical professionals, pharmacies, or wholesalers.

Manner and Means of the Conspiracy

4. It was part of the conspiracy that, beginning on or about May 7, 2010, defendant **MERWIN MARC SNYDER** received at his residence in Egg Harbor Township, New Jersey various parcels from India through the United States Postal Service that were accompanied by incomplete or misleading United States Customs declarations.

5. It was further part of the conspiracy that these parcels received by defendant **MERWIN MARC SNYDER** contained prescription drugs, including unapproved generics that

contained the active ingredients in the popular brand name drugs Viagra, Cialis, and Levitra, as well as unapproved Mifepristone and Misoprostol.

6. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** re-packaged these wholesale quantities of drugs into smaller amounts and dispensed them to consumers.

7. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** did not seek FDA approval to market these drugs nor was he licensed as a pharmacist in the State of New Jersey or otherwise authorized to prescribe or dispense prescription drugs.

8. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** shipped in interstate commerce through the United States Postal Service misbranded drugs that did not bear the FDA-approved labeling.

9. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** was paid for his services by unnamed foreign co-conspirators.

10. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** attempted to conceal his criminal acts by placing fraudulent names and return addresses on the packages containing drugs that defendant **SNYDER** dispensed and distributed through the United States Mail.

11. It was further part of the conspiracy that defendant **MERWIN MARC SNYDER** caused to be shipped approximately 27 parcels addressed to him in Egg Harbor Township, New Jersey that contained over 25,000 tablets of unapproved generic drugs containing Tadalifil (active ingredient in Cialis) and 28,000 tablets of Sildenafil Citrate (active ingredient in Viagra).

Overt Acts

12. In furtherance of the conspiracy and in order to effect its unlawful objects, defendant **MERWIN MARC SNYDER** and his co-conspirators committed and caused to be committed the following overt acts, in the District of New Jersey and elsewhere:

a. On or about May 7, 2010, unindicted co-conspirator P.P.W., sent from Chennai, India to defendant **MERWIN MARC SNYDER** in Egg Harbor Township, New Jersey, two parcels totaling 90 packages of an unapproved prescription drug labeled Medical Termination of Pregnancy ("MTP") combination pack (5 pills/pack) of "Mifepristone" and "Misoprostol" manufactured by Cipla LTD in Sikkim, India.

b. On or about September 12, 2011, defendant **MERWIN MARC SNYDER** shipped via Express Mail No. EG341207232US from the Cologne, New Jersey Post Office to Illinois ten 100 mg tablets of the unapproved prescription drug Filagra (an unapproved generic drug with the same active ingredient in Viagra) which was manufactured by Dadha Parma in India. Defendant **SNYDER** provided the fraudulent return address: "M.C.," on Chapel Avenue, Cherry Hill, New Jersey.

c. On or about September 26, 2011, defendant **MERWIN MARC SNYDER** shipped ten 100 mg tablets of Filagra 100 (an unapproved generic drug with the same active ingredient in Viagra) manufactured by Centurion Laboratories in India from the Cologne, New Jersey Post Office to Illinois. Defendant **SNYDER** provided the fraudulent return address of "M.C.," on Chapel Avenue, Cherry Hill, New Jersey.

d. On or about October 14, 2011, defendant **MERWIN MARC SNYDER** shipped ten 100 mg tablets of Filagra 100 (unapproved generic containing the same active ingredient as Viagra) manufactured by Centurion Laboratories in India via Priority Mail No.:

03111660000249830488 from the Cologne, New Jersey Post Office to Connecticut. Defendant **SNYDER** provided the fraudulent return address on the package as "L.D." on Frontage Road, Cherry Hill, New Jersey.

e. On or about February 9, 2012, defendant **MERWIN MARC SNYDER** mailed one ten count blister pack of blue oval-shaped tablets identified as "Filagra 100" (unapproved generic containing the same active ingredient as Viagra) manufactured by Centurion Laboratories, Ltd., from the U.S. Post Office in Cologne, New Jersey to Woodbury, New Jersey. The parcel bore "Delivery Confirmation No. 0311 1660 0002 1218 2170," and listed a fraudulent return address of "M.C.," on Chapel Avenue, Cherry Hill, New Jersey.

In violation of Title 18, United States Code, Section 371.

COUNTS 2 - 4
[18 U.S.C. § 545 – Smuggling of Misbranded Drugs]

1. Paragraphs 1 and 3 through 13 of Count 1 of this Indictment are hereby re-alleged and incorporated as if set forth in full herein.

2. On or about the dates set forth below, in the District of New Jersey and elsewhere, defendant

MERWIN MARC SNYDER

did fraudulently and knowingly import and bring into the United States merchandise contrary to law, that is prescription drugs that were misbranded for lacking adequate directions for use.

Count	*Approximate Date*	*Merchandise*
2	December 9, 2010	2400 pills of Filagra
3	February 10, 2011	200 pills of Filagra
4	February 22, 2012	3000 pills of Tadalista

In violation of Title 18, United States Code, Section 545, and Title 18, United States Code, Section 2.

COUNT 5
[21 U.S.C. § 331(c) – The Receipt and Delivery of Misbranded Drugs]

1. Paragraphs 1 and 3 through 13 of Count 1 of this Indictment are hereby re-alleged and incorporated as if set forth in full herein.

2. On or about February 9, 2012, in the District of New Jersey and elsewhere, defendant

MERWIN MARC SNYDER

did, with the intent to defraud or mislead, receive misbranded drugs in interstate commerce, namely, 10 pills of Filagra 100, and deliver or proffer delivery of them for pay or otherwise.

In violation of Title 21, United States Code, Sections 331(c), 352(f), 352(a), and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 6 - 9
[21 U.S.C. § 331(k) – Misbranding By Dispensing Prescription Drugs Without A Valid Prescription]

1. Paragraphs 1 and 3 through 13 of Count 1 of this Indictment are hereby re-alleged and incorporated as if set forth in full herein.

2. On or about the dates set forth below, in the District of New Jersey and elsewhere, defendant

MERWIN MARC SNYDER

did, with the intent to defraud and mislead, cause prescription drugs to become misbranded after they moved in interstate commerce and while they were held for sale (whether or not the first sale) by dispensing them without the valid prescription of a practitioner licensed by law to administer such drugs.

Count	Date	Prescription Drug	Dispensed
6	September 12, 2011	10 tablets of Filagra 100 manufactured in India	Illinois
7	September 26, 2011	10 tablets of Filagra 100 manufactured in India	Illinois
8	October 14, 2012	10 tablets of Filagra 100 manufactured in India	Connecticut
9	February 9, 2012	10 tablets of Filagra 100 manufactured in India	New Jersey

In violation of Title 21, United States Code, Section 331(k), and Title 18, United States Code, Section 2.

COUNTS 10-13
[21 U.S.C. § 331(a) – Introducing Misbranded Drugs into Interstate Commerce]

1. Paragraphs 1 and 3 through 13 of Count 1 of this Indictment are hereby re-alleged and incorporated as if set forth in full herein.

2. On or about the dates set forth below, in the District of New Jersey and elsewhere, defendant

MERWIN MARC SNYDER

did, with the intent to defraud and mislead, introduce, deliver for introduction, and cause the introduction and delivery for introduction into interstate commerce drugs, devices and cosmetics that were adulterated and misbranded as defined in Title 21, United States Code, Section 352(f)(1), in that the labeling did not bear adequate directions for use:

Count	*Approximate Date*	*Merchandise*
10	September 12, 2011	Ten 100mg tablets of Filagra 100 (Sildenafil Citrate)
11	September 26, 2011	Ten 100mg tablets of Filagra 100 (Sildenafil Citrate)
12	October 14, 2011	Ten 100mg tablets of Filagra 100 (Sildenafil Citrate)
13	February 9, 2012	Ten 100mg tablets of Filagra 100 (Sildenafil Citrate)

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATION
[18 U.S.C. § 981(a)(1)(C); 18 U.S.C. § 982(a)(1); 28 U.S.C. § 2461(c)]

1. The allegations contained in Counts 1 through 13 of this Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeiture.

2. Pursuant to Federal Rule of Criminal Procedure 32.2(a), the United States of America gives notice to the Defendant that, in the event of a conviction of any of the offenses charged in Counts 1 through 4 of this Indictment, the United States intends to forfeit the property further described in this NOTICE OF FORFEITURE.

3. A defendant who is convicted of an offense in violation of 18 U.S.C. § 545, or a conspiracy to violate of 18 U.S.C. § 545, shall forfeit to the United States of America, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to such violation(s).

4. The property to be forfeited includes, but is not limited to, the following:

a. Any quantities of Viagra, Cialis, Levitra, Mifepristone, Misoprostol, Artesunate injections, Tretinoin Gel and Cream, and various "imitation" drugs containing the active ingredients of the trade named drugs, including but not limited to, the named "Filagra, Tadalista, Viprogra, Filitra, Sildigra, Combipack Mifepristone/Misoprostol, Artesunate Injection, Tretinoin Cream, Tretinoin Gel," which, between May 7, 2010 and July 18, 2013 were misbranded when introduced into or while in interstate commerce, or after shipment in interstate commerce, or which may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce.

b. T.D. Bank, N.A. account no. 7867517463, in the name of **MERWIN MARC SNYDER**

c. $340,053.18 in United States currency

5. If by any act or omission of defendant **MERWIN MARC SNYDER,** any of the property subject to forfeiture described in paragraph 4 herein - -

a. Cannot be located upon the exercise of due diligence;

b. Has been transferred or sold to, or deposited with, a third party;

c. Has been placed beyond the jurisdiction of the Court;

d. Has been substantially diminished in value; or

e. Has been commingled with other property which cannot be divided without difficulty, the United States of shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United America States Code, Section 2461(c).

Pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(1), and Title 28, United States Code, Section 2461(c).

A TRUE BILL

FOREPERSON

PAUL J. FISHMAN
United States Attorney

CASE NUMBER: 15-

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

MERWIN MARC SNYDER

INDICTMENT FOR
18 U.S.C. § 371
18 U.S.C. § 545
21 U.S.C. § 331(a), (c), and (k)
Forfeiture
18 U.S.C. § 2

A True Bill,

_____
Foreperson

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